BEFORE THE
STATE BOARD OF PHARMACY
STATE OF MISSOURI

IN RE:	)	
	)	
MISSOURI CVS PHARMACY, LLC	)	
d/b/a CVS PHARMACY #5655	)	Case No. 2017-002916 - V1
Permit No. 2009008292	)	
1901 West Kansas Street	)	
Liberty, MO 64068	)	
	)	

SETTLEMENT AGREEMENT BETWEEN MISSOURI BOARD OF PHARMACY AND CVS #5655

Come now Missouri CVS Pharmacy, LLC d/b/a CVS Pharmacy #5655 ("Respondent" or the "Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing before the Board, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record concerning the charges pending against it; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided him by operation of law, Respondent knowingly and voluntarily

waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the Violation Complaint filed against it with the Board. For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2009008292, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to §338.110, RSMo,[1] for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent is licensed by the State of Missouri as a pharmacy, permit number 2009008292. Respondent's permit was at all times relevant herein current and active.

3. Respondent's permit to practice pharmacy was on probation until on or about April 26, 2020.

Prior Disciplinary Action

4. On or about March 14, 2018, Respondent signed a Settlement Agreement (the "Agreement") with the Board which contained a Joint Stipulation of Facts, Joint Conclusions of Law and a Joint Agreed Disciplinary Order for failing to maintain adequate security of controlled substances resulting in significant losses of controlled substances.

5. The Agreement was executed by the Board on April 12, 2018. The Agreement went into full effect on April 27, 2018.

[1] All statutory references are to the Revised Statutes of Missouri (2016) unless otherwise indicated.

6. Pursuant to the Agreement, Respondent's license was placed on probation for two (2) years and imposed terms of discipline which Respondent agreed to follow during the term of probation.

7. The Disciplinary Order requires that:

> A.2. Respondent shall comply with all applicable provisions of Chapter 338, Chapter 195, Chapter 196 and all applicable federal and state pharmacy/drug laws and regulations and all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

8. The Disciplinary Order also provides:

> A.9. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

9. The Disciplinary Order further provides:

> B. . . . that in the event the Board determines that Respondent has violated any term or condition of this Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke or otherwise lawfully discipline Respondent.

10. The Disciplinary Order finally provides:

> D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. . . .

Subsequent Violations

July 24, 2018 Inspection

11. On or around July 24, 2018, Board Inspector Andi Miller conducted a routine inspection of the Pharmacy.

12. Inspector Miller observed numerous violations of federal and state statutes and regulations.

13. She issued a Compliance Notice to the Pharmacy for certain violations at the end of the inspection.

a. Failure to produce technician list

14. During Inspector Miller's July 24, 2018 inspection of the Pharmacy, it was unable to produce its list of pharmacy technicians.

15. Missouri law requires the Pharmacist-in-Charge (PIC) of the Pharmacy :

> (BB) Maintain a current list of all personnel employed by the pharmacy as pharmacy technicians. The list shall include the name, registration number or a copy of an application for registration that has been submitted to the board and a description of duties to be performed by each person contained on the list. 20 CSR 2220-2.090(2)(BB).

16. By failing to produce the list of the pharmacy technicians, the PIC of the Pharmacy was in violation of 20 CSR 2220-2.090(2)(BB).

b. Failure to Maintain Pharmacy in Sanitary Condition

17. During her July 24, 2018, inspection of the Pharmacy, Inspector Miller observed dust and debris on the shelves and floor.

18. She also observed candy wrappers and three (3) loose tablets – amoxicillin, amitiza, doxycycline – on the shelves.

19. The compounding counter near the sink also was sticky.

20. Missouri law requires that pharmacies be kept in sanitary condition, to-wit:

> (F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions. 20 CSR 2220-2.010(1)(F).

21. Dust and debris on the floor and shelves, loose tablets on the shelves and sticky surfaces does not represent clean and sanitary conditions in the Pharmacy in violation of 20 CSR 2220-2.010(1)(F).

22. A Compliance Notice was issued to the Pharmacy because this was a repeat violation.

c. Deficient policy and procedures

23. During Inspector Miller's July 24, 2018 inspection of the Pharmacy, she reviewed the Pharmacy's policies and procedures for its electronic recordkeeping system (ERS).

24. Missouri law requires:

> (4) Pharmacies maintaining an ERS shall establish written policies and procedures for the use of the ERS which shall include policies and procedures for reviewing compliance with the requirements of this rule and for storing, retrieving, and recovering digitized images. The policy and procedure manual shall be reviewed annually and shall be available to representatives of the board upon request. 20 CSR 2220-2.083(4).

25. The Pharmacy violated Missouri law by failing to maintain policies and procedures on its ERS that covered all aspects mandated by 20 CSR 2220-2.083(4).

d. Adulterated drug products

26. During her inspection, Inspector Miller observed three (3) open cholestyramine powder packets stored in the compounding cabinet with no closure.

27. Missouri law deems a drug adulterated "[i]f If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. . . ." § 196.095(2), RSMo

28. A drug stored in an inappropriate container or with an inadequate closure is adulterated under § 196.095(2), RSMo.

29. Missouri law prohibits the following with regard to adulterated drug products :

> (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
> (2) The adulteration or misbranding of any food, drug, device, or cosmetic. § 196.015(1)-(2).

30. The Pharmacy violated § 196.015(1)-(2), RSMo by selling, delivering, holding, and/or offering adulterated drug products for sale.

31. A drug stored in an inappropriate container or with an inadequate closure also is adulterated under federal law, to-wit:

> A drug or device shall be deemed to be adulterated—
> **(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture**
> (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health 21 U.S.C. § 351(a)(2)(A).

32. Federal law prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a).

33. The Pharmacy violated 21 U.S.C. § 331(a) by introducing and/or delivering adulterated drug products into interstate commerce.

34. A Compliance Notice was issued by Inspector Miller because this was a repeat violation.

e. Outdated Drug Products in Active Inventory

35. During Inspector Miller's July 24, 2018 inspection, she also reviewed the active inventory of the Pharmacy.

36. Inspector Miller found at least thirteen (13) expired drug products in active inventory. The expired drug products consisted of two (2) compounded products, ten (10) legend

drug products/compounding supplies and one (1) legend product missing a lot number and expiration date.

37. Missouri law requires:

> (V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items. 20 CSR 2220-2.090(2)(V).

38. Missouri law also states:

> (6) Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are for employee personal use or that are outdated, distressed, misbranded or adulterated. 20 CSR 2220-2.010(6)

39. By failing to keep expired drug products out of the active inventory, the Pharmacy was in violation of 20 CSR 2220-2.010(6) and 2.090(2)(V).

40. This was a repeat violation.

f. Prepackaging Violations

41. During her July 24, 2018 inspection, Inspector Miller reviewed the prepackaged drug products in the Pharmacy's ScriptPro robot.

42. Missouri law allows pharmacies to prepackage drug products under certain conditions, to wit:

> (1) A pharmacist or pharmacy may prepackage drugs for other than immediate dispensing purposes provided that the following conditions are met:
>
> > (D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

(2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer's container and is placed in a dispensing container for other than immediate dispensing to a patient. 20 CSR 2220-2.130(1)(D).

43. The Pharmacy failed to record and/or maintain lot numbers for most of the drug products in the ScriptPro in violation of 20 CSR 2220-2.130(1)(D).

g. Dispensing errors

44. During her July 24, 2018 inspection of the Pharmacy, Inspector Miller also reviewed the Pharmacy's dispensing records and observed three (3) dispensing errors.

45. She observed that prescription no. 1869627 dispensed on May 8, 2018 was written for cephalexin 250mg #28, but was dispensed by the Pharmacy in the incorrect strength of 500mg.

46. She observed that prescription no. N1904150 dispensed on July 19, 2018 for oxycodone/apap 5mg/325mg #90 was prescribed to be taken as needed ("1prn q6hr"), but was dispensed as a scheduled medication ("1 q6hr").

47. She observed that prescription no. N1904479 dispensed on July 20, 2018 for hydrocodone/apap 10mg/325mg #90 was prescribed to be taken every four (4) hours as needed ("1 po q4hr prn pain"), but was dispensed as four (4) times daily ("1 po qid prn pain").

48. Inspector Miller issued a quality assurance report to the Pharmacy on the date of the inspection for each of these three (3) dispensing errors.

49. The pharmacist who dispensed these three (3) prescriptions failed to properly exercise professional discretion when the prescriptions were dispensed with incorrect strengths or instructions, possibly resulting in patient harm.

h. Prescription violations

50. During her July 24, 2018 inspection of the Pharmacy, Inspector Miller also reviewed the Pharmacy's controlled substance prescription records.

51. Inspector Miller discovered that e-prescribed controlled substance prescription nos. C1897119 and C18962327 had been converted to facsimiles.

52. Federal law does not allow e-prescriptions to be converted to other formats, to wit:

> (f) An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (e.g., facsimile) for transmission. 21 CFR §1311.170(f)

53. By dispensing controlled substances based on prescriptions written in electronic form that had been converted to facsimiles, the Pharmacy violated 21 CFR 1311.170(f).

54. Inspector Miller also observed that the Pharmacy failed to verify the origin of faxed prescription no. C1897751.

55. Missouri law requires:

> (1) Definitions.
>
> (A) Electronic image transmission--An exact visual image of a paper prescription or medication order that is electronically received by a pharmacy from a licensed prescriber or the prescriber's authorized agent (e.g., a facsimile/scan).
>
> (2) Prescriptions or medication orders may be transmitted to a pharmacy by the prescriber or the prescriber's authorized agent as an electronic image transmission or an electronic prescription.
>
> (A) Electronic image transmissions and electronic prescriptions must contain all information required by state and federal law, including, designation of whether generic substitution is authorized. Electronic image transmissions must be formatted as required by section 338.056, RSMo, and bear the prescriber's manual or electronic signature.
>
> (B) Controlled substance prescriptions and medication orders must comply with state and federal controlled substance laws and regulations and must be signed in accordance with state and federal law.
>
> (C) A pharmacist shall be responsible for verifying the authenticity of any electronic image transmission or electronic prescription prior to dispensing by taking measures which, in his/her professional judgment, may be necessary to ensure the prescription or medication order was initiated or authorized by the prescriber.
>
> 20 CSR 2220-2.085(2)

56. By failing to verify the origin of faxed prescription no. C1897751, the Pharmacy violated 20 CSR 2220-2.085(2).

57. Since this was a repeat violation, Inspector Miller issued a Compliance Notice to the Pharmacy for this violation.

i. Failure to Offer Patient Counseling

58. During her July 24, 2018 inspection, Inspector Miller observed a failure by a pharmacist or a supervised intern to offer patient counseling to all patients who picked up prescriptions.

59. Inspector Miller observed a technician counseling a patient on the telephone at 1:07 p.m. discussing antifungal and steroid creams; at 1:33 p.m. relaying information from a pharmacist to patient about when to start birth control packet; and at 1:40 p.m. at the drive-up window regarding storage and administration of reconstituted antibiotic liquid.

60. Missouri law requires:

> (1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained . . . 20 CSR § 2220-2.190(1)

61. By failing to offer each patient of the Pharmacy counseling by a pharmacist or by a supervised intern, the Pharmacy was in violation of 20 CSR 2220-2.190(1).

62. This was a repeat violation and the second consecutive Compliance Notice issued to the Pharmacy for this violation.

j. Inability to Access OTC Pseudoephedrine Sales Records

63. During her July 24, 2018 inspection, Inspector Miller was not given access to the Pharmacy's over-the-counter pseudoephedrine sales records.

64. Missouri law requires that pharmacists use the real-time electronic pseudoephedrine tracking system established and maintained by the Missouri Department of Health and Senior Services (DHSS). 19 CSR 30-1.074(3)(C).

65. It further requires that "[a]ccess to the database and controlled substance records shall be made available to those agencies with authority under Chapter 195 and Chapter 338, RSMo." 19 CSR 30-1.074(3)(N)1

66. By failing to provide Inspector Miller access to the over-the-counter pseudoephedrine database during the inspection, the Pharmacy was in violation of 19 CSR 30-1.074(3)(N)1.

67. Since this was a repeat violation, Inspector Miller issued a Compliance Notice to the Pharmacy for this violation.

k. Immunization Protocol Violations

68. During her July 24, 2018 inspection, Inspector Miller reviewed the Pharmacy's immunization per protocol and vaccine administration records.

69. Many of the Pharmacy's vaccine administration records were incomplete or inaccurate in that they were missing documentation of the patient's primary care physician; they improperly documented the quantity of Shingrix administered as 1.00mL instead of .5mL; and they lacked the patient's date of birth, the dose administered to the patient and the lot number and expiration date of the vaccine.

70. Missouri law gives a licensed pharmacist the authority to give immunizations, by protocol, to-wit:

1. The "practice of pharmacy" means . . . he administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule. . . "§338.010.1, RSMo.[2]

71. However, Missouri law requires very specific requirements to be met in order for pharmacists at the Pharmacy to be authorized to give immunizations, to-wit:

> (1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.
>
> > (A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (12) years of age.
> >
> > (B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirement.
>
> (2) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualification under subsections 4(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines.
>
> (3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.
>
> (4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:
>
> > (A) Hold a current unrestricted license to practice pharmacy in this state;
> >
> > (B) Hold a current cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;
> >
> > (C) Successfully complete a certificate program in the administration of vaccines accredited by the Accreditation

[2] In in effect through August 27, 2018.

Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy;

(D) Maintain documentation of the above certifications;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

(F) Provide documentation of Subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized vaccine(s);

5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing the length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street address of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it and at any time.

(6) Record Keeping

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection 6(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(D) The records required by this rule shall be maintained securely and confidentially as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the prescription files of the pharmacy. If the vaccine is not being administered on behalf of the pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine; and
2. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the State Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline. 20 CSR 2220-6.050.[3]

72. The Pharmacy's vaccine administration records were deficient because they did not identify the patient's primary care physician; they improperly stated the quantity of vaccine

[3] All citations to 20 CSR § 2220-6.050 refer to the regulation in effect through September 29, 2018.

administered; and they lacked the patient's date of birth, the dose administered and the lot number and expiration date of the vaccine in violation of 20 CSR 2220-6.050(6)(A)1-4.

l. Compounding Violations

73. During her July 24, 2018 inspection of the Pharmacy, Inspector Miller reviewed the Pharmacy's compounded drug records.

74. For compounded drug products, Missouri law requires:

> (7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.
>
> > (A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:
> >
> > > 6. The identity of the source, lot number and the beyond use date of each drug product/ingredient, as well as an in-house lot number and beyond use date for bulk compounded products; and
> >
> > (D) Any excess compounded products shall be stored and accounted for under conditions dictated by its composition and stability characteristics to insure its strength, quality and purity. Excess product shall be labeled with the name of the drug(s), an in-house lot number and beyond-use date.
> > 20 CSR 2220-2.400(7)(A), (D)

75. Inspector Miller observed that the compound log maintained by the Pharmacy was incomplete in that it did not contain the batch number and beyond use date of a compound returned to stock. This information also was not contained on the label of the returned to stock compound.

76. The Pharmacy's failure to maintain compound logs as well as labels with all information required by law violated 20 CSR 2220-2.400(7)(A)6 and (D).

August 9, 2019 Inspection

77. On or around August 9, 2019, Inspector Andi Miller conducted another routine inspection of the Pharmacy.

78. She observed additional and repeated violations of federal and state statutes and regulations.

79. She issued a Compliance Notice to the Pharmacy for certain violations at the end of the inspection.

m. Failure to display pharmacist photo

80. During her August 19, 2019 inspection, Inspector Miller observed that the license for pharmacist B.A. had no accompanying photograph displayed.

81. Missouri laws requires:

> (K) All pharmacists will be required to have a photo of themselves not smaller than two inches by two inches (2" x 2") in the upper right-hand corner of the current renewal licenses. This photo and license renewal shall be conspicuously exposed in the pharmacy or drug store or place of business in which the pharmacist is employed as required by law. 20 CSR 2220-2.010(k).

82. The Pharmacy's failure to display a photograph with pharmacist B.A.'s license violated 20 CSR 2220-2.010(k).

n. Failure to Maintain Pharmacy in Sanitary Condition

83. During her August 9, 2019 inspection of the Pharmacy, Inspector Miller observed dust on the shelves and drug containers.

84. She also observed that the Fillmaster tip and drip pan needed to be cleaned to remove dried medication residue or replaced to prevent cross-contamination.

85. Excessive dust on shelves and drug containers and dried medication residue on pharmacy equipment does not represent clean and sanitary conditions in the Pharmacy in violation of 20 CSR 2220-2.010(1)(F).

o. Adulterated drug products

86. During her August 9, 2019 inspection, Inspector Miller again observed an open cholestyramine powder packet stored in the compounding cabinet with no closure.

87. A drug stored in an inappropriate container or with an inadequate closure is adulterated under § 196.095(2), RSMo.

88. The Pharmacy violated § 196.015(1)-(2), RSMo by selling, delivering, holding, and/or offering adulterated drug products for sale.

89. A drug stored in an inappropriate container or with an inadequate closure also is adulterated under 21 U.S.C. § 351(a)(2)(A).

90. The Pharmacy violated 21 U.S.C. § 331(a) by introducing and/or delivering adulterated drug products into interstate commerce.

91. This was a repeat violation and the second consecutive Compliance Notice issued to the Pharmacy for this violation.

p. Outdated Drug Products in Active Inventory

92. During Inspector Miller's August 9, 2019 inspection, she again found at least nine (9) expired drug products in active inventory.

93. By failing to keep expired drug products out of its active inventory, the Pharmacy was in violation of 20 CSR 2220-2.010(6) and 2.090(2)(V).

94. This was a repeat violation.

q. Dispensing errors

95. During her August 9, 2019 inspection, Inspector Miller observed four (4) dispensing errors.

96. She observed that prescription no. C2081555 dispensed on July 16, 2019, written for clonazepam 1mg #60, was prescribed as "1.5-2 po qhs prn insomnia," but was dispensed as "1-2 po qhs prn insomnia."

97. She observed that prescription no. C2083103 dispensed on July 19, 2019, for alprazolam .25mg #30 was prescribed to be taken as needed ("1 tablet 1 hour before public appearance daily as needed"), but was dispensed as a scheduled medication ("1 tablet 1 hour before public appearance daily").

98. She observed that prescription no. 2087613 dispensed on July 29, 2019, was written for fluconazole 100mg #8, but was dispensed by the Pharmacy in the incorrect strength of 150mg with no change to directions.

99. She observed that prescription no. 2087572 dispensed on July 29, 2019, for silenor 3mg #30 was prescribed as "1 qd qhs prn," but, but was dispensed as "1 prn" without giving directions as to frequency.

100. Inspector Miller issued a quality assurance report to the Pharmacy on the date of the inspection for each of these four (4) dispensing errors.

101. The pharmacists who dispensed these four (4) prescriptions failed to properly exercise professional discretion when the prescriptions were dispensed with incorrect strengths or instructions, possibly resulting in patient harm.

r. Prescription violations

102. During her inspection on August 9, 2019, Inspector Miller also observed that the Pharmacy failed to verify the origin of faxed prescription nos. C2083021 and 2087869.

103. By failing to verify the origin of faxed prescription nos. C2083021 and 2087869, the Pharmacy violated 20 CSR 2220-2.085(2).

104. This was a repeat violation and the second consecutive Compliance Notice issued to the Pharmacy for this violation.

s. Failure to Offer Patient Counseling

105. During her August 9, 2019 inspection, Inspector Miller again observed throughout the duration of her inspection a failure to offer patient counseling by a pharmacist or supervised intern to all patients.

106. By failing to offer each patient counseling by a pharmacist or by a supervised intern, the Pharmacy was in violation of 20 CSR 2220-2.190(1).

February 6, 2020 Inspection

107. On or around February 6, 2020, Inspector Andi Miller conducted another routine inspection of the Pharmacy.

108. She observed additional and repeated violations of federal and state statutes and regulations.

109. She issued a Compliance Notice to the Pharmacy for certain violations at the end of the inspection.

t. Failure to Maintain Pharmacy in Sanitary Condition

110. During her February 6, 2020 inspection of the Pharmacy, Inspector Miller again observed dust buildup on the drug shelves.

111. She also observed again that the Fillmaster tip and drip pan needed to be cleaned to remove dried medication residue or to be replaced to prevent cross-contamination.

112. Dust buildup on shelves and dried drug product on pharmacy equipment does not represent clean and sanitary conditions in the Pharmacy in violation of 20 CSR 2220-2.010(1)(F).

113. Another Compliance Notice was issued for this repeat violation.

u. Outdated Drug Products in Active Inventory

114. During her February 6, 2020 inspection, Inspector Miller also found one (1) expired drug product in active inventory.

115. By failing to keep expired drug products out of the active inventory, the Pharmacy violated 20 CSR 2220-2.010(6) and 2.090(2)(V).

v. Repackaging Violations

116. During her February 6, 2020 inspection of the Pharmacy, Inspector Miller discovered two (2) drug containers in active inventory with no labels.

117. Missouri law allows the Pharmacy to repackage drug products, but has specific labeling requirements, to wit:

> (D) Any prepackaged drug must have a label affixed to it which contains, at a minimum, the name, strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection. 20 CSR 2220-2.130(1)(D).

118. The Pharmacy violated 20 CSR 2220-2.130(1)(D) by storing two (2) drug containers in its active inventory without labels.

119. Inspector Miller issued a Compliance Notice to the Pharmacy for this violation.

w. Dispensing errors

120. During her February 6, 2020 inspection, Inspector Miller observed four (4) additional dispensing errors.

121. She observed that prescription no. N2182311 dispensed on January 26, 2020, written for morphine sulfate IR 15mg #12 was prescribed "as needed" ("1 po tid PRN PAIN"), but was dispensed as a scheduled medication ("1 po tid").

122. She observed that prescription no. 2182847 dispensed on January 27, 2020, for ibuprofen 800mg #30 was prescribed as "1 q 6hr x48hr after procedure, then 1 6hr PRN PAIN," but was dispensed with incomplete directions as "1 q 6hr x2das after, then 1 q 6hr after."

123. She observed that prescription no. N2184885 dispensed on January 30, 2020, for hydrocodone/apap 5mg/325mg #90 was prescribed "as needed" ("1 po q 8hr PRN pain"), but was dispensed as a scheduled medication ("1 po q 8hr").

124. She observed that prescription no. 2184518 dispensed on January 30, 2020, for ibuprofen 600mg #30 was prescribed as "1 q 6hr prn pain", but was dispensed as "1 q 4hr prn pain."

125. Inspector Miller issued a quality assurance report to the Pharmacy on the date of the inspection for each of these four (4) dispensing errors.

126. The pharmacists who dispensed these four (4) prescriptions failed to properly exercise professional discretion when the prescriptions were dispensed with incorrect strengths or instructions, possibly resulting in patient harm.

JOINT CONCLUSIONS OF LAW

127. Respondent is subject to discipline under 20 CSR § 2220-2.010(1)(O) which states:

> (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

128. Respondent is liable for violations of Chapter 338 or other relevant laws because, "any permit holder . . . at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation." § 338.210.5, RSMo.

129. Respondent's actions violate the terms of the Agreement in that it has failed to comply with all provisions of Chapter 338, Chapter 195, Chapter 196, and all applicable federal and state drug laws, rules and regulations.

130. Since Respondent violated the disciplinary terms contained in the Agreement, the Board is authorized under the Agreement to impose further discipline on Respondent's permit in accordance with Section 338.055.3, RSMo, which provides, in pertinent part:

> . . . the board may impose additional discipline on a licensee, registrant or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. §338.055.3, RSMo.

131. Moreover, cause exists to discipline Respondent's permit under §338.055.2(5), (6), (12), (13) and (15), RSMo, which states:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one of any combination of the following causes.
>
> * * *
>
> (5) Incompetence, misconduct. . . in the performance of the functions or duties of any profession licensed or regulated by this chapter;
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
>
> * * *
>
> (12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;
>
> (13) Violation of any professional trust or confidence;
>
> * * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government . . .

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045, RSMo

A. Respondent's pharmacy permit number 2009008292 shall be placed on **PROBATION for a period of THREE (3) YEARS**. The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

The following terms apply for the entire disciplinary period.

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.

4. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

5. Respondent shall be audited and report to the Board as follows:

   a. Within 30 days of the Effective Date of this Order, Respondent shall be audited by a District Professional Practice Leader (DPPL) using the Board's Pharmacy Self-Assessment Form. The DPPL will prepare a list of corrective actions and a timeline for completion of those actions.

   b. Both the audit report and the list of corrective actions and timeline shall be provided to the Board within 60 days.

c. The DPPL shall provide quarterly reports to the Board on compliance with the necessary corrective actions for the duration of the probationary term.

d. Monthly audits of Respondent shall be completed using the list of corrective actions prepared in the initial audit by the District Leader (DL), the DPPL or a Quality Assurance Technician.

e. The pharmacist-in-charge ("PIC") for Respondent will conduct bi-monthly self-inspections using the Board's Pharmacy Self-Assessment Form.

f. All audits and self-inspections shall be documented and available in the pharmacy's records for review by the Board upon request.

6. Within 60 days of the Effective Date of this Order, the current PIC for Respondent shall receive concentrated, in-person, compliance training from a DPPL. Any new PIC for Respondent during the probationary period also shall receive the same training within 30 days of appointment to the position. The training shall be at least two (2) hours on the following subjects:

a. Recordkeeping requirements, to specifically include the location and appropriate maintenance of records of pharmacy technicians, the policies and procedures for the electronic recordkeeping system, the over-the-counter pseudoephedrine sales records, the vaccine administration records and the photos of pharmacists.

b. "Bay a Day" program, a daily rotation check for outdated drugs and cleaning of drug storage areas.

c. Daily cleaning routines to maintain clean and sanitary conditions for other pharmacy areas, including the sink, compounding area, Fillmaster and floors.

d. Proper compounding procedures, to include disposal of open excess product and appropriate labeling of compounded products.

e. Proper filling of the ScriptPro machine, to include proper labeling of all cells with lot numbers for the drug products.

f. Procedures for entry and verification of prescription elements to ensure quality assurance on dispensed prescriptions.

g. State and federal laws on controlled prescriptions, including conversion of electronic prescriptions and verification of faxed prescriptions.

h. Requirements for counseling of all patients by a pharmacist or supervised intern.

i. Requirements for repackaging and labeling of products.

7. Within 30 days of the Effective Date of this Order, the PIC for Respondent shall block off no less than two (2) hours per week to be dedicated to review and improvement of pharmacy operations and compliance during the first year of probation. During these blocked off time periods, the PIC shall not be involved in dispensing activities.

8. Within 90 days of the Effective Date of this Order, all pharmacists employed at Respondent shall receive group training of at least one (1) hour on the subjects listed in item # 6(a)-(i), above. All pharmacists hired to a full time position at Respondent shall receive the same training within 30 days of the start of such employment. All pharmacists employed at Respondent shall receive a refresher training on these subjects annually for the duration of the probationary period.

9. Respondent shall not serve as an intern training facility for Missouri interns.

10. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

11. All required prescription records and records relating to immunizations or medication administered by medical prescription order shall be produced on inspection or at the request of the Board.

12. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

13. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said discipline, Respondent's permit as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that Respondent has violated any term or condition of this Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke or otherwise lawfully discipline Respondent.

C. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

D. No order shall be entered by the Board pursuant to the preceding paragraph of this Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

E. The terms of this Settlement Agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement not any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent, its successors, assigns, and its attorneys, do hereby waive and release, acquit and forever discharge the Board, its respective members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including but not limited to, any claims for attorney's fees and expenses, including any claims

pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

The Settlement Agreement goes into effect on the date it is signed by the Board's Executive Director.

RESPONDENT

MISSOURI CVS PHARMACY, LLC
D/B/A CVS PHARMACY #5655

By: _____
As authorized representative for
CVS Pharmacy #5655

Printed: Leo Lariviere, Dir. Regulatory Affairs

Date: 2/22/21

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____
Kimberly Grinston
Executive Director

Date: 2/24/2021

NEWMAN, COMLEY & RUTH P.C.

By: _____
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